K010965

SUMMARY OF SAFETY AND EFFECTIVENESS
Alaris Medical Systems A-line AEP Monitor

SUBMITTER INFORMATION

A.	Company Name:	Alaris Medical Systems
B.	Company Address:	10221 Wateridge Circle San Diego, CA 92121-2733
C.	Company Phone: Company Fax:	(858) 458-7563 (858) 458-6223
D.	Contact Person:	Renée Fluet Principle Regulatory Affairs Specialist Alaris Medical Systems
E.	Date Summary Prepared:	March 22, 2001

DEVICE IDENTIFICATION

A.	Generic Device Name:	Electroencephalograph and Evoked Response Auditory Stimulator
B.	Trade/Proprietary Name:	A-line AEP Monitor
C.	Classification:	Class II
D.	Product Code:	GWQ and GWJ

SUBSTANTIAL EQUIVALENCE

The Alaris Medical Systems A-line AEP Monitor is of comparable type and is substantially equivalent to the following predicate devices:

Predicate Device	Manufacturer	510(k) No.	Date Cleared
A-2000 EEG Monitor with BIS	Aspect Medical Systems	K974496	2/6/1998
EEG module	Datex-Ohmeda	K000892	6/16/2000

DEVICE DESCRIPTION

The A-line AEP Monitor is a non-invasive measurement tool for use by trained healthcare professionals to measure the level of consciousness (LOC) in all areas of the hospital. The A-line Monitor performs fast extraction (2 to 6 seconds) of Auditory Evoked Potentials (AEP) which is the brains' response to acoustic stimuli of the hearing nerve. Based on the AEP extraction, an ARX-Index (AAI) is calculated, which is used in the estimation of LOC. The A-line AEP Monitor displays the ARX-Index and EEG signals, but does not perform any data interpretation (i.e., all data interpretation is performed by a physician).

The following accessories are provided with the A-line AEP Monitor:

- A-line Headphones (reusable)
- A-line cables (RS-232, Patient Cable, AC Power Cord)
- Optional Patient / History Information Template (CD)
- Alaris Medical Systems recommends the A-line electrodes for use with the A-line AEP Monitor (part number ALE025).

INTENDED USE

The A-line AEP Monitor is intended for use in monitoring the state of the brain by data acquisition of EEG signals of the anesthetized or sedated patient in all areas of the

hospital. The A-line AEP Monitor is a non-invasive measurement tool to be used by a trained professional to measure the level of consciousness during general anesthesia or sedation by use of AEP.

TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the A-line AEP Monitor and the predicate device has been performed. The results of this comparison demonstrate that the A-line AEP Monitor is equivalent to the marketed predicate devices

PERFORMANCE DATA

The performance data indicate that the A-line AEP Monitor meets all specified requirements, and is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 7 2001

Ms. Renée L. Fluet
Principal Regulatory Affairs Specialist
ALARIS Medical Systems, Inc.
10221 Wateridge Circle
San Diego, California 92121

Re: K010965
Trade/Device Name: A-line AEP Monitor
Regulation Number: 882.1400, 882.1900
Regulatory Class: II
Product Code: GWQ, GWJ
Dated: March 30, 2001
Received: April 2, 2001

Dear Ms. Fluet:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K010965 (To Be Assigned By FDA)

Device Trade Name: A-line AEP Monitor

Indications For Use: The A-line AEP Monitor is indicated for use in monitoring the state of the brain by data acquisition of EEG signals in the intensive care unit, operating room, and for clinical research. The AEP, a processed EEG variable, may be used as an aid in monitoring the consciousness effects of certain anesthetic agents.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE) for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010965

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)